IFU of MAISNEO™

I.V. Cannula without Injection Port & with small Wings

Manufactured by Mais India Medical Devices Pvt. Ltd.

Intended Use :

I.V. Cannula/ Catheter (with or without safety feature) is a device for access to the human circulatory system for introduction of fluids or medications and/or withdrawal of blood samples.

Materials Used :

Polypropylene, Polyoxymethylene, FEP/PUR/PTFE (Fluorinated Ethylene Propylene / Polyurethane / Polytetrafluoroethylene), High-density Polyethylene (HDPE), Barium Suphate ($BaSO_4$).

Indications:

· Infusion of I.V. Solutions.
· Intermittent intravenous drugs administration.

Contra Indications:-

· Product should not be used on patients with known hypersensitivity to any of the materials used.
· Administration of high viscous fluids.
· Large blood transfusions.

Instructions for use:

1. Sanitize your hands using an alcohol-based hand cleanser.
2. Position the arm so that it is comfortable for the patient and identify a vein.
3. Apply the tourniquet.
4. Locate an accessible (visible) and suitable peripheral vein and confirm by palpation.
5. Re-check the vein.
6. Put on your gloves, clean the patient's skin with an alcohol wipe and let it dry.
7. Select a suitable size of I.V. Cannula/Catheter (with or without safety feature) based on patient's age group at the discretion of a Qualified doctor or a paramedic. Visually inspect the packaging to ensure its integrity.
8. Remove the cannula from its packaging and remove the needle cover ensuring not to touch the needle.
9. Do not touch the catheter.
10. Hold the I.V. Cannula/ Catheter (with or without safety feature) at body and needle hub projection.
11. Insert the needle with the bevel facing upwards at a low angle. Upon primary flashback lower the angle almost parallel to the skin (If familiar with the device, expect flashback slightly delayed in the flashback chamber.)
12. Advance the cannula slightly, 2 to 3 mm, to ensure the cannula tip is in the vein.
13. Stabilize the cannula.
14. Hold the I.V. Cannula/ Catheter (with or without safety feature) properly / firmly at Catheter Hub with one hand & with the other hand withdraw the needle back 2 to 3 mm with prompt continuous motion parallel to the skin, ensuring that the catheter hub does not come out from the vein while the needle is being retracted from the Catheter Hub.
15. Secondary flashback between the needle and cannula will confirm correct placement in the vein.
16. Advance the cannula completely into the vein.
17. Release the tourniquet, apply pressure to the vein at the tip of the cannula and remove the needle fully by pressing the vein at the insertion point with the help of the index finger of the other hand, to stop the blood loss.
18. Apply taping over the wings of the cannula at the insertion site of the skin.
19. Remove the threaded stopper from the needle and attach it to the end of the cannula.
20. Carefully dispose of the needle in a sharps bin.
21. Connect to other infusion devices (as appropriate).
22. Apply a sterile dressing to the cannula to fix it in place.

Medical conditions:

· Read the "Instructions for Use" carefully before using the product.
· The use of the product is restricted to a qualified doctor or a paramedic staff.

Warnings:

1. The use of this product is restricted to a qualified doctor or a paramedic.
2. Read instructions before use.
3. MAIS INDIA disclaims any responsibility for possible consequences resulting from improper use.
4. The product should not be reprocessed.
5. Visually inspect and carefully check the product and packaging before use.
6. Improper transport and handling may cause structural and / or functional damage to device or its packaging.
7. The product is non-toxic, sterile & non-pyrogenic.
8. Do not clean or re sterilize. For single use only. Discard after use.
9. Re-use of single-use devices creates a potential risk (i.e bloodstream infection) to patient or user.
10. If the device is reused, then it may cause a bacterial infection in patient, and also may lead to contamination and/or impairment of functional capability, which may in turn lead to patient injury.
11. After withdrawal, do not reintroduce the steel needle into the catheter, as the latter may be cut off, leading to catheter embolism.
12. If there is any change in expected performance of the device or in case of any malfunction, the device should be immediately removed & sent back to supplier for an investigation to be conducted.
13. Store in a cool & dry place.
14. Do not expose to heat or direct sunlight.
15. The product should be used immediately after its packaging is opened.

Cautions:

· Never try to reinsert a partially or completely withdrawn needle. Discard the partially or completely withdrawn needle and use a new device.
· In case of non-detection of flashback, seems to be failure Venipuncture, remove the cannula and dispose as per hospital norms and retry with a new device instead of the used one.
· Do not use if the packaging is damaged.
· During removal of catheter after its intended purpose, precautions must be taken as.
· Ensure that any sharp edges must not be used to remove the I.V. Fixator.
· Discard after single use.

Target Age Group:
For Neonates

Duration of Contact of Device:
Up to 72 Hours for best performance.

Storage conditions:
Store at a temperature between +10°C and +40°C, humidity between 40% to 60%, in a dry place and away from sunlight.

Device Life:
05 Years

Explanation of symbols used:

Symbols	Title of the Symbol	Symbols	Title of the Symbol
	Consult instructions for use (Indicates the need for the user to consult the instructions for use)		Latex free (Indicates a medical device that is Latex free)
	Caution (To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.)		Date of manufacture (Indicates the date when the medical device was manufactured)
	Sterilized using ethylene oxide (Indicates a medical device that has been sterilized using ethylene oxide)		Use-by date (Indicates the date after which the medical device is not to be used)
	Do not re-sterilize (Indicates a medical device that is not to be re-sterilized)		Batch Number (Indicates the manufacturer's batch number so that the batch or lot can be identified)
	Do not re-use (Indicates a medical device that is intended for one single use only)		CE Mark
	Non-pyrogenic (Indicates a medical device that is non- pyrogenic)		Keep away from sunlight (Indicates a medical device that needs protection from light sources)

Symbols	Title of the Symbol	Symbols	Title of the Symbol
	Do not use if packaging is damaged and consult instructions for use. (Indicates a medical device that should not be used if its packaging has been damaged or opened, and that the user should consult the instructions for use for additional information)		Authorized representative in the European Community / European Union (Indicates the authorized representative in the European Community/ European Union) OBELIS S.A. Boulevard Général Wahis 53, 1030 Brussels, Belgium Contact Number: +32(2)73 25 954 Email ID: regulatory@obelis.net Website: www.obelis.net
	Keep dry (Indicates a medical device that needs to be protected from moisture)		Manufacturer (Indicates the medical device manufacturer) Manufacturing Unit: 525P, Sector-37, Pace City II, Gurgaon, Haryana-122001, India. Contact Details.: +91 8527589990 Fax No.: 0124 404 7533 Email ID: info@maisindia.com Website:www.maisindia.com
	Single sterile barrier system (Indicates a single sterile barrier system)		Country of manufacture (To identify the country of manufacture of products)
	Unique Device Identifier (Indicates a carrier that contains Unique Device Identifier information)		Medical device (Indicates the item is a medical device)
	Humidity limitation (Indicates the range of humidity to which the medical device can be safely exposed.		Temperature limit (Indicates the temperature limits to which the medical device can be safely exposed.
	Reference number (Indicates the manufacturer's catalogue number so that the medical device can be identified)		Fragile, handle with care (Indicates a medical device that can be broken or damaged if not handled carefully)
	This way up		

Manufactured by:
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